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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
SHIBUYA, MARK LANCE	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,052	NEW ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *13-22* is/are objected to.

8)☒ Claim(s) *1-12, 23-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-7, 11 and 12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 2, claim(s) 1-7, 11 and 12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a mono- or poly-saccharide.

Group 3, claim(s) 1-7, 11 and 12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a mono- or poly-nucleotide.

Group 4, claim(s) 1-7, 11 and 12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a sterol.

Group 5, claim(s) 1-7, 11 and 12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a water-soluble vitamin.

Group 6, claim(s) 1-7, 11 and 12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a porphyrin or haem nucleus.

Group 7, claim(s) 1-7, 11 and 12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a metal ion chelate.

Group 8, claim(s) 1-7, 11 and 12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a water-soluble drug.

Group 9, claim(s) 1-7, 11 and 12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a hormone.

Group 10, claim(s) 1-7, 11 and 12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is an enzyme substrate.

Group 11, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 12, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a mono- or poly-saccharide.

Group 13, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a mono- or poly-nucleotide.

Group 14, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a sterol.

Group 15, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a water-soluble vitamin.

Group 16, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a porphyrin or haem nucleus.

Group 17, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a metal ion chelate.

Group 18, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a water-soluble drug.

Group 19, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a hormone.

Group 20, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is an enzyme substrate.

Group 21, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 22, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a mono- or poly-saccharide.

Group 23, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a mono- or poly-nucleotide.

Group 24, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a sterol.

Group 25, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a water-soluble vitamin.

Group 26, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group*

that comprises a hydroxy acid, and wherein the head group is a porphyrin or haem nucleus.

Group 27, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a metal ion chelate.

Group 28, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a water-soluble drug.

Group 29, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a hormone.

Group 30, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is an enzyme substrate.

Group 31, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 32, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a mono- or poly-saccharide.

Group 33, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a mono- or poly-nucleotide.

Group 34, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a sterol.

Group 35, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a water-soluble vitamin.

Group 36, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a porphyrin or haem nucleus.

Group 37, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a metal ion chelate.

Group 38, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a water-soluble drug.

Group 39, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a hormone.

Group 40, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is an enzyme substrate.

Group 41, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 42, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a mono- or poly-saccharide.

Group 43, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a mono- or poly-nucleotide.

Group 44, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a sterol.

Group 45, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a water-soluble vitamin.

Group 46, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group*

that comprises a polyethylene glycol, and wherein the head group is a porphyrin or haem nucleus.

Group 47, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a metal ion chelate.

Group 48, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a water-soluble drug.

Group 49, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a hormone.

Group 50, claim(s) 1-12, drawn to compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is an enzyme substrate.

Group 51, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 52, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a mono- or poly-saccharide.

Group 53, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a mono- or poly-nucleotide.

Group 54, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a sterol.

Group 55, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a water-soluble vitamin.

Group 56, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a porphyrin or haem nucleus.

Group 57, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a metal ion chelate.

Group 58, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a water-soluble drug.

Group 59, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a hormone.

Group 60, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is an enzyme substrate.

Group 61, claim(s) 23-30, drawn to methods for producing comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 62, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a mono- or poly-saccharide.

Group 63, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a mono- or poly-nucleotide.

Group 64, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a sterol.

Group 65, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group

and a *spacer group* that comprises an amino acid, and wherein the head group is a water-soluble vitamin.

Group 66, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a porphyrin or haem nucleus.

Group 67, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a metal ion chelate.

Group 68, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a water-soluble drug.

Group 69, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a hormone.

Group 70, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is an enzyme substrate.

Group 71, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 72, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a mono- or poly-saccharide.

Group 73, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a mono- or poly-nucleotide.

Group 74, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a sterol.

Group 75, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a water-soluble vitamin.

Group 76, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a porphyrin or haem nucleus.

Group 77, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a metal ion chelate.

Group 78, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a water-soluble drug.

Group 79, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a hormone.

Group 80, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is an enzyme substrate.

Group 81, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 82, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group

and a *spacer group* that comprises a sugar, and wherein the head group is a mono- or poly-saccharide.

Group 83, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a mono- or poly-nucleotide.

Group 84, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a sterol.

Group 85, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a water-soluble vitamin.

Group 86, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a porphyrin or haem nucleus.

Group 87, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a metal ion chelate.

Group 88, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a water-soluble drug.

Group 89, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a hormone.

Group 90, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is an enzyme substrate.

Group 91, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group

and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 92, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a mono- or poly-saccharide.

Group 93, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a mono- or poly-nucleotide.

Group 94, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a sterol.

Group 95, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a water-soluble vitamin.

Group 96, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a porphyrin or haem nucleus.

Group 97, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a metal ion chelate.

Group 98, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a water-soluble drug.

Group 99, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a hormone.

Group 100, claim(s) 23-30, drawn to methods for producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is an enzyme substrate.

Group 101, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 102, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a mono- or poly-saccharide.

Group 103, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a mono- or poly-nucleotide.

Group 104, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a sterol.

Group 105, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a water-soluble vitamin.

Group 106, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a porphyrin or haem nucleus.

Group 107, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a metal ion chelate.

Group 108, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct

conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a water-soluble drug.

Group 109, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is a hormone.

Group 110, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, and wherein the head group is an enzyme substrate.

Group 111, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 112, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a mono- or poly-saccharide.

Group 113, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a mono- or poly-nucleotide.

Group 114, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a sterol.

Group 115, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a water-soluble vitamin.

Group 116, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group*

that comprises an amino acid, and wherein the head group is a porphyrin or haem nucleus.

Group 117, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a metal ion chelate.

Group 118, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a water-soluble drug.

Group 119, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is a hormone.

Group 120, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises an amino acid, and wherein the head group is an enzyme substrate.

Group 121, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 122, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a mono- or poly-saccharide.

Group 123, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a mono- or poly-nucleotide.

Group 124, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct

conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a sterol.

Group 125, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a water-soluble vitamin.

Group 126, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a porphyrin or haem nucleus.

Group 127, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a metal ion chelate.

Group 128, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a water-soluble drug.

Group 129, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is a hormone.

Group 130, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a hydroxy acid, and wherein the head group is an enzyme substrate.

Group 131, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 132, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct

conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a mono- or poly-saccharide.

Group 133, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a mono- or poly-nucleotide.

Group 134, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a sterol.

Group 135, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a water-soluble vitamin.

Group 136, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a porphyrin or haem nucleus.

Group 137, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a metal ion chelate.

Group 138, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a water-soluble drug.

Group 139, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is a hormone.

Group 140, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a sugar, and wherein the head group is an enzyme substrate.

Group 141, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is an amino acid, peptide, or peptide analogue.

Group 142, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a mono- or poly-saccharide.

Group 143, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a mono- or poly-nucleotide.

Group 144, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a sterol.

Group 145, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a water-soluble vitamin.

Group 146, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a porphyrin or haem nucleus.

Group 147, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a metal ion chelate.

Group 148, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group*

that comprises a polyethylene glycol, and wherein the head group is a water-soluble drug.

Group 149, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is a hormone.

Group 150, claim(s) 31, drawn to a method for producing a molecule for interaction with a ligand, comprising producing compositions comprising a plurality of distinct conjugates, each conjugate comprising a head group, a tail group and a *spacer group* that comprises a polyethylene glycol, and wherein the head group is an enzyme substrate.

The inventions listed as Groups 1-150 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature of a composition for interacting with a ligand, which composition comprises a non-covalent association of a plurality of distinct conjugates, each conjugate comprising a head group and a tail group, wherein the tail groups of the conjugates form a hydrophobic aggregation and the conjugates are movable within the association, is taught by Yager et al., US 5,851,536. Yager et al., US 5,851,536, at col. 2, lines 16-37, col. 3, line 63 – col. 4, line 67, col. 5, lines 38-44, Fig.s 4, 5, 8, col. 6, lines 57-62, col. 8, lines 1-7, col. 14, lines 28-48, col. 15, line 58 – col. 16, line 49, col. 17, lines 54-64, col. 21, lines 9-48, col. 24, lines 39-50, teach compositions comprising "therapeutics" (Th) that are head groups that can be a peptide or polypeptide, high axial ratio forming molecules (HARFM) that are lipid tail groups and spacers. Th can be covalently bound to HARFM. The HARFMs can form aggregates in water because of their hydrophobic tails and can form liposomes, micelles, and lamellar associations. See Figure 5. The compositions of Yager et al. are the same as the compositions of the claimed invention. Therefore, absent evidence to the contrary, the conjugates of Yager are movable in their association and in the presence of a ligand, at least two of the head groups would be appropriately positioned to form an epitope capable of interacting with the ligand more strongly than each of head groups individually.

Furthermore, the head and spacers groups of the claimed inventions comprise molecules that do not share a common core structure and do not share common properties. Therefore these claimed inventions further lack unity of invention.

2. Claims 13-22 are objected to and are not subject to the instant requirement for restriction/election. Claims 13-22 provides for the **use** of conjugates, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. When claims 13-22 are amended so as to recite active, positive steps delimiting how this use is actually practiced, said claims will be considered for restriction or election of species.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A. Compositions and methods thereof, wherein the tail is a straight or branched-chain fatty acid; alcohol or aldehyde having at least 8 carbon atoms; a lipidic amino acid analogue; a prostaglandin; a leukotriene; a mono- or di-glyceride; a sterol; a sphingosine or ceramide derivative; or a silicon or halogen-substituted derivative of the lipophilic group or wherein each lipophilic group comprises a C_{10} to C_{14} fatty acid.

B. Compositions and methods thereof, wherein the non-covalent association comprises a lamellar structure, a micelle or a liposome.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

1. Species Requirement A: Claims 6 and 7 recite the molecular structure of the tail group compositions of the claimed inventions.

2. Species Requirement B: Claim 11 recites the non-covalent association of the composition of the claimed inventions.

The following claim(s) are generic: 1, 6, 7, 8-10, and 23.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The head and spacers groups of the claimed inventions comprise molecules that do not share a common core structure and do not share common properties.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Shibuya
Examiner
Art Unit 1639

ms

PADMASHRI PONNALURI
PRIMARY EXAMINER